

REMARKS

Claims 10, 18, 19, 22-24 and 32 were pending prior to this Response. By the present communication, no claims have been added and claim 10 has been amended to recite Applicants' invention with greater particularity. Specifically, the claim amendments are intended to clarify that (i) the claimed isolated polynucleotides are shorter than the full length coding region of the dnaJ gene (*i.e.*, they consist essentially of nucleotides that have a nucleotide sequence that encodes the dnaJp1 peptide), and (ii) the peptide encoded by the isolated polynucleotides has the amino acid sequence of dnaJp1, *i.e.*, it is the dnaJp1 peptide.

Applicants respectfully request entry of the amendments set forth in this response under 37 CFR §1.116. The amendments do not raise any issues of new matter and the amended claims do not present new issues requiring further consideration or search. Support for the amended claim language may be found, among others, at page 11, lines 13-18, and at page 14, lines 19-26. The claim amendments do not constitute new matter, being fully supported by the Specification and original claims. Accordingly, claims 10, 18, 19, 22-24 and 32 are currently pending in this application.

Rejection Under 35 U.S.C. § 103

Applicants respectfully traverse the rejection of claims 10, 18, 20, 22 and 32 under 35 U.S.C. 103(a) as allegedly being unpatentable over Bardwell et al. (Accession No. HHECDJ and The Journal of Biological Chemistry, Vol. 261, No: 4, pp. 1782-1785, 1986). Applicants submit that Claim 20 has been previously canceled, rendering the rejection moot as pertains to claim 20.

The burden of proof in establishing a *prima facie* case of obviousness under § 103 clearly rests with the Patent Office. *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). In establishing a *prima facie* case, the Patent Office, among other things, must show that (1) the prior art would have suggested to those of ordinary skill in the art that they should make the claimed invention and (2) that the prior art would have revealed a reasonable expectation of

success. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). “Both the suggestion and the reasonable expectation of success must be found in the prior art, not in the applicant’s disclosure.” *Id.* Thus, “particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.” *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). Further, when relying on the knowledge of persons of ordinary skill in the art, the Patent Office must “explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination.” *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). “The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with.” *In re Sang Su Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002) (citations omitted).

To date, the Patent Office has failed to provide objective evidence of any suggestion or motivation in the prior art to combine and modify the particular references cited by the Office. Instead, the Office has simply recited elements gleaned from the references, and stated that the combination of these elements would have been obvious to one skilled in the art. It is well settled that the Patent and Trademark Office cannot pick and choose among the individual elements of assorted prior art references to recreate the claimed invention. *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 887 (Fed. Cir. 1988). In addition, it is now well established that “[b]road conclusory statements regarding the teaching of multiple references standing alone are not ‘evidence’.” *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999); see also *In re Kotzab*, 217 F.3d at 1370. “Th[e] factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority.” *In re Sang Su Lee* 277 F.3d at 1343-44. Without such objective evidence to combine the references, it is inferred that the references were selected with the assistance of hindsight. *In re Rouffet*, 149 F.3d at 1358. It is well-established that the use of hindsight in the selection of references that comprise a case of obviousness is forbidden. *Id.*

Applicants respectfully submit that Accession No. HHECDJ is the full length amino acid sequence of the protein *E. coli* K12 dnaJ. While the full length nucleic acid sequence encoding Accession No. HHECDJ is set forth in Figure 2 of Bardwell, the reference does not disclose, nor even suggest, an isolated polynucleotide that consists essentially of a string of nucleotides that encode the dnaJp1 peptide, i.e., a peptide that consists of the amino acid sequence of SEQ ID NO: 4.

As amended, claim 10 of the claimed invention recites isolated polynucleotide *consisting essentially of* nucleotides having a nucleotide sequence that encodes a bacterial dnaJp1 peptide consisting of the amino acid sequence of SEQ ID NO: 4. It is noteworthy to mention that the law is clear as to what is meant by the transition "consisting essentially of" in the context of a patent claim. Specifically, it permits inclusion of components not listed in the claim, provided that they do not "materially affect the basic and novel properties of the invention." *PPG Indus. V. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed.Cir.1998). Accordingly, Applicants respectfully submit that amended claim 10 does not include the full coding region of the *E. coli* dnaJ protein disclosed by Bardwell.

To the extent that Bardwell discloses fragments of the *E. coli* dnaJ gene (on page 1783, as cited in the Action), the disclosure is only in the context of a restriction map and the sequencing strategy for obtaining the nucleotide sequence of the full length dnaJ gene (see Bardwell, Figure 1, p. 1783). Bardwell is absolutely silent with regard to any isolated fragment within the full length nucleic acid sequence of Accession No. HHECDJ, which would lead one of skill in the art to isolate the specific peptide from positions 181-225. Additionally, the cited reference does not teach or suggest a vector containing a polynucleotide sequence encoding a dnaJ peptide. Thus, Applicants submit that *prima facie* obviousness of the invention over Bardwell, has not been shown by the Examiner. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103 for alleged lack of patentability are respectfully requested.

In re Application of:
Carson and Albani
Application No.: 09/616,247
Filed: July 14, 2000
Page 7

PATENT
Attorney Docket No.: UCSD1370-5

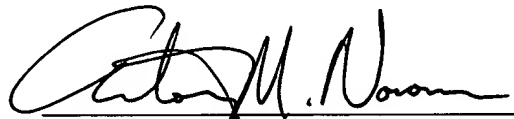
CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that claims 10, 18, 19, 22-24 and 32 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending. If the Examiner would like to discuss any of the issues raised in the Office Action, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Enclosed is Check No. 574728 in the amount of \$760.00 (\$250.00 for the Notice of Appeal fee and \$510.00 for the Three (3) Months Extension of Time fee). The Commissioner is hereby authorized to charge for any additional required fees, or credit any overpayments to Deposit Account No. 07-1896.

Respectfully submitted,

Date: February 23, 2005



Antony M. Novom, J.D.
Registration No. 45,517
Telephone: (858) 638-6641
Facsimile: (858) 677-1465

DLA PIPER RUDNICK GRAY CARY US LLP
4365 Executive Drive, Suite 1100
San Diego, California 92121-2133
USPTO Customer Number 28213